

Exhibit 12

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May 30, 2014

VIA HAND DELIVERY and ELECTRONIC MAIL

Chris J. Tardio
Gideon Cooper & Essary
315 Deaderick St., Suite 1100
Nashville, Tennessee 37238

Re: New England Compounding Center Litigation, MDL No. 2419

Dear Chris:

You have previously requested that the Plaintiffs' Steering Committee produce to you that the "NECC Inspection Report" contemplated by MDL Order No. 6. To be clear, because of the subsequent bankruptcy of NECC, no formal inspection report was ever completed.

Warmest regards,



BENJAMIN A. CASTEL

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June 2, 2014

sent via email only

Ben Gastel
Branstetter, Stranch & Jennings, PLLC
227 Second Ave. N.
Fourth Floor
Nashville, TN 37061-1631

Re: *New England Compounding Pharmacy, Inc.*
No. 13-2419

Dear Ben:

Thank you for your letter of May 30, 2014, regarding our request for the report from the Plaintiffs' experts' inspection of NECC. You state that "because of the subsequent bankruptcy of NECC, no formal inspection report was ever completed." Your response raises a number of questions in light of the Court's orders related to the inspection and the PSC's affirmative statements about the results of the inspection.

In the PSC's "status report" filed March 12, 2014, the PSC stated unequivocally that an inspection was conducted by "Plaintiffs' consultants" on December 18-21, 2012.¹ The report summarily referenced the results as having "found dozens of bacteria and fungus inside the NECC facility, including in the cleanrooms and HVAC system."²

¹ MDL Dkt. 1005 [3/12/14], page 16-17.

² MDL Dkt. 1005, page 17.

The order signed by Judge Boal in *Erkan*³ setting the parameters of the inspection⁴ specifically requires that “Plaintiffs’ Inspection findings will be recorded in writing, with sketches where appropriate.”⁵ Additionally, the order repeatedly refers to a “report” being produced from the inspection.⁶ These recordation provisions were included in the order *proposed by the Plaintiffs*⁷ and are consistent with the Plaintiffs’ affirmative representation that a “primary objective” of the inspection was to “[d]ocument all conditions found.”⁸ The signed order even specifically sets out what information will be recorded.⁹

Judge Boal’s order *requires* that the Plaintiffs’ counsel provide “an inspection report (or reports) that sets forth statements of fact about the observed conditions, including raw data, observations of fact, measurements and test results.”¹⁰

There is no dispute that these orders governing the inspection and, more importantly for our request, the production of the “statements of fact about the observed conditions, including raw data, observations of fact, measurements and test results[,]” apply in the MDL.¹¹

I find it impossible to believe that a *four-day* inspection of NECC, *inside and out*, conducted by Plaintiffs’ consultants, involving “detailed daily protocol schedules[,]”¹² resulted in no documents capturing the observed conditions, measurements, and testing. This is why I was confused by your letter and concerned with the qualification in your statement.

My questions:

1. What documentation (specifically, but not limited to, of “conditions found”), including anything you contend is privileged¹³, was created by the consultants during the inspection from December 18-21, 2012?

³ No. 1:12-cv-12052-RWZ.

⁴ “Order Setting Protocol for Onsite Inspection and Testing of New England Compounding Center, Framingham, MA” [Dkt. 126, 12/18/12].

⁵ *Erkan* Dkt. 126, page 6.

⁶ See, e.g., *Erkan* Dkt. 126 [12/18/12], page 6, 7, 11.

⁷ *Erkan* Dkt. 125.

⁸ *Erkan* Dkt. 126, page 5.

⁹ *Erkan* Dkt. 126, 6-8.

¹⁰ *Erkan* Dkt. 126, page 11-12.

¹¹ MDL Order No. 6, MDL Dkt. 209 [6/28/13].

¹² MDL Dkt. 1005, page 17.

¹³ The orders made a distinction between documentation of the mental impressions and interpretations of the consulting experts (not discoverable) and observations of facts and measurements (discoverable). If you are contending that documents were created but are privileged, we are still entitled to some explanation of the nature of the documents such that we can assess the application of the privilege. FRCP 26(b)(5). Plus, this may very well be the limited situation where we are unable to obtain the information via other means. FRCP 26(b)(4)(A)(ii).

2. If *no* documentation was created during the inspection, why not, specifically considering that the order required it?
3. If *documentation was created by the consultants but not formalized in a report*, why was no formal report created, specifically considering that the order required it?¹⁴
4. Did the consulting experts create any draft(s) of a report? If so, where is that draft, and was it ever provided to plaintiffs' counsel or to defendants' counsel?
5. How were "statements of fact about the observed conditions, including raw data, observations of fact, measurements and test results" recorded during the inspection, and where are those documents (or data) now?
6. Has the PSC (or, at the time, interim liaison plaintiffs' counsel) provided any documentation from the inspection – a formal report or otherwise – to plaintiffs' counsel or defendants' counsel? If so, what was provided and when?

I need the above information in order to determine whether to file a motion. Please respond to these inquiries and send me dates to meet and confer on this prior to June 16 so that we can file a motion to be heard with Judge Boal on July 17, if necessary.

Thank you.

Very truly yours,



Chris J. Tardio

CJT/ao

¹⁴ I simply do not understand your statement that a formal report was not created due to the NECC bankruptcy. I am not sure what the bankruptcy had to do with creating an inspection report.

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June 27, 2014

VIA HAND DELIVERY and ELECTRONIC MAIL

Chris J. Tardio
Gideon Cooper & Essary
315 Deaderick St., Suite 1100
Nashville, Tennessee 37238

Re: New England Compounding Center Litigation, MDL No. 2419

Dear Chris:

This letter is meant to respond to your June 2, 2014 letter related to your requests that the Plaintiffs' Steering Committee (the "PSC") identify and produce to you the documents and other information in the PSC's possession related to the December, 20 2012 inspection (the "Inspection") of the NECC facility in Framingham, Massachusetts (the "NECC Facility").

At the outset, I need to clarify my May 30, 2014 letter. I never stated nor intended to convey that the PSC had "no documents" from the Inspection as you indicate in your June 2 letter. You had repeatedly requested the "NECC Inspection Report" contemplated by MDL Order No. 6. As I previously indicated, NECC's subsequent bankruptcy changed the landscape of this litigation, and as a result the PSC chose not to incur the considerable expense of having a formal inspection report of the entire Inspection generated.

Obviously the PSC has documentation related to the Inspection, including the following:

- A memo related to the pressure measurements at the NECC Facility;
- Results, testing documents, and chain of custody forms from environmental microbiology testing;
- Approximately 4,000 photographs; and
- A video of the NECC Facility on the day of the Inspection.

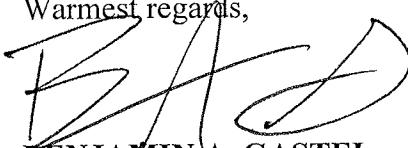
Letter to Chris J. Tardio

June 27, 2014

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The PSC has produced these documents to some of the defendants participating in the mediation program in accordance with the Court's Mediation Order (Dkt. No. 394).

To date, the PSC has not received a formal discovery requests requiring the production of these materials in this litigation. Although the PSC has consistently maintained that full discovery is open and should proceed against all Unaffiliated Defendants (and has even sought to lift the stay over the Affiliated Defendants), you have taken the position that discovery is not open, and we are to await a Rule 26(f) discovery conference before you will participate in discovery, or even serve your initial disclosures. The PSC is prepared to produce all non-privileged documents in its possession, custody, or control related to the Inspection upon an acknowledgement from you that discovery is open (as made clear in MDL Order No. 7) and service of an appropriate discovery request.

Warmest regards,

BENJAMIN A. GASTEL